To whom it may concern,

Please find below comments on behalf of Novo Nordisk A/S to the draft:

"Harmonised requirements for non-investigational medicinal products in CTA submissions (Jun 2010)"

Section Nr	Comment
2	The guideline specifies that the sponsor implement a system allowing traceability of NIMPs. When trials include subjects with chronic disease who per protocol are requested to continue with their pre-trial treatment for the chronic disease, Novo Nordisk understand that to be in compliance with the guideline requires recording of name (trade/brand or generic), strength and doses of the NIMP taken by each patient. If the above interpretation is not correct then the guideline should specify the level of details required, and allow for an exception if a justification is provided by the sponsor in the CTA.
3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.2.1, 4.2.2	In all sections simplified dossiers are possible in case the NIMP is marketed. However in cases where a product is approved but not marketed (yet) the availability of a simplified dossier should be present. I therefore propose to exchange: NIMP is a marketed medicinal product to : NIMP is an approved medicinal product.
3.2.5	Dossier requirement for NIMP not approved/marketed (API not used before) is not described. Presumable the same requirements as in section 3.2.4.

My apologies for providing the comments 1 day passed deadline. I hope you will be able to include them in the consolidated set of comments.

Kind regards

Lill-Brith

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